

**UNITED STATES DISTRICT COURT FOR THE  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

<b>IN RE: NATIONAL PRESCRIPTION</b>	)	<b>MDL No. 2804</b>
<b>OPIATE LITIGATION</b>	)	
	)	<b>Case No. 1:17-md-2804</b>
<b>THIS DOCUMENT RELATES TO:</b>	)	
<i>Track Three Cases</i>	)	<b>Judge Dan A. Polster</b>

**DEFENDANTS HBC SERVICE COMPANY AND GIANT EAGLE, INC.'S  
BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT**

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## **INTRODUCTION**

Giant Eagle is entitled to summary judgment on Lake and Trumbull Counties’ claim alleging “that Defendants’ violations of anti-diversion laws gave rise to a public nuisance.” Doc. # 3403 at 5 (describing Doc. # 3327 at ¶¶ 71-599, 616-654 (Count XI)). As evidenced by the 100-plus in-depth DEA and Ohio Board of Pharmacy (“BOP”) inspections conducted by a bevy of experienced and thorough DEA Diversion Investigators and Ohio BOP Agents, Giant Eagle has a more than decade-long record of “full compliance” with applicable anti-diversion laws. As such, Giant Eagle cannot be liable for the alleged public nuisance.

Giant Eagle’s record of “full compliance” is no exaggeration. The DEA—the agency charged with enforcing the Controlled Substances Act (“CSA”)—conducted at least seven in-depth physical investigations of Giant Eagle’s distribution operations relating to the controlled substances at issue in CT3, including its Suspicious Order Monitoring systems (“SOM systems”). The DEA repeatedly determined, in writing and without qualification, that Giant Eagle was in “**full compliance**” with the governing CSA security regulations.<sup>1</sup> Similarly, the Ohio Board of Pharmacy (“BOP”)—the agency charged with enforcing Ohio’s drug and pharmacy laws—conducted ninety-two (92) inspections of Giant Eagle’s pharmacies in the Counties, including their dispensing and security systems, and repeatedly determined that Giant Eagle was acting lawfully and in compliance with applicable regulations. Ultimately, rather than establish any regulatory violation, the undisputed evidence establishes the opposite. Giant Eagle did more—much more—to prevent diversion than the law requires, and neither its distribution nor dispensing operations

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<sup>1</sup> The DEA also conducted at least four additional investigations relating to Giant Eagle’s distribution of List I chemicals, and always found Giant Eagle in compliance with similar security regulations.

bear *any* resemblance to the bad distributors and pharmacies that were the primary drivers of opioid diversion in these two Counties and throughout the country.

A record of “full compliance,” as this Court has recognized, provides registrants like Giant Eagle with “safe harbor” immunity from absolute nuisance liability. *See* Doc. # 3403 at 29-30 (relying upon *Brown v. County Commissioners*, 622 N.E. 2d 1153 (Ohio Ct. App. 1993) and *Cincinnati v. Beretta*, 768 N.E.2d 1136 (Ohio 2002) and holding that “under Ohio law, ‘safe harbor’ immunity from absolute nuisance liability is available only to those who perform in accordance with their applicable licensing regulatory obligations.”). Giant Eagle justifiably relied on these agencies’ repeated determinations in building, maintaining, *and improving* its anti-diversion controls. The Counties’ attempt to retroactively change the results of Giant Eagle’s 100-plus regulatory inspections from “pass” to “fail” also violates Giant Eagle’s due process rights because Giant Eagle never received “fair notice” that the agencies’ determinations could or would be changed based solely on the opinion of hired experts in private litigation a decade later.

Giant Eagle is also entitled to summary judgment because the Counties have not and cannot offer any evidence that Giant Eagle’s distribution and dispensing of controlled substances was the *proximate cause* of a significant and unreasonable interference with a public right.

Giant Eagle also moves, at minimum, for partial summary judgment for all conduct relating to its GERX distribution facility, which began distributing Schedule II controlled substances in March 2016, because there is a complete failure of proof that GERX violated *any* regulation. Indeed, the Counties’ DEA expert could not even opine on—let alone find any regulatory violations relating to—GERX.

The Counties’ case against Giant Eagle should end with the same conclusion as the DEA reports finding Giant Eagle in “full compliance” with the security regulations: “This case is

closed.” The Court should grant summary judgment in favor of Giant Eagle on Count XI and dismiss Giant Eagle from this case.<sup>2</sup>

## **I. STATEMENT OF UNDISPUTED MATERIAL FACTS**

Giant Eagle is a Pittsburgh-based, family-owned regional supermarket chain that offers a wide array of products, including prescription and over-the-counter medication sold through in-store pharmacies. In total, Giant Eagle operates approximately 220 of these in-store pharmacies, only 12-14 of which were located in Lake and Trumbull Counties during the relevant time period.<sup>3</sup>

The Counties’ distribution case has focused almost exclusively on HBC, Giant Eagle’s warehouse distribution center located in Washington, Pennsylvania. From November 2009 until September 2014, HBC distributed only one product relevant to this litigation, and only to its own in-store pharmacies: generic hydrocodone combination products (“HCPs”). SJ-Ex. 18 (Durr Tr. at 121:3-125:17); Doc. # 3327 at ¶¶ 390-412 (no allegations against Giant Eagle post-September 2014); SJ-Ex. 19 (Giant Eagle 30(b)(6) Tr. at 23:10-19, 73:17-74:8). HBC stopped distributing Schedule III HCPs in late September 2014, one week before the DEA reclassified HCPs from Schedule III to Schedule II. SJ-Ex. 19 (Giant Eagle 30(b)(6) Tr. at 273:5-11). In January 2016, Giant Eagle opened a new warehouse known as Giant Eagle Rx Distribution Center (“**GERX**”), which started distributing Schedule II-V controlled substances to Giant Eagle’s in-store pharmacies—and only Giant Eagle pharmacies—in March 2016. SJ-Ex. 19 (Giant Eagle 30(b)(6) Tr. at 80:18-81:4).<sup>4</sup>

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<sup>2</sup> Giant Eagle assumes the facts stated herein as true for the purposes of this Motion only and reserves all rights to challenge the Court’s prior legal rulings (which are accepted for purposes of this Motion only). To avoid redundancy, Giant Eagle incorporates herein the well-known standard for granting summary judgment under Fed. R. Civ. P. 56 that the parties and Court have previously articulated in similar filings.

<sup>3</sup> Two stores closed during the relevant time period.

<sup>4</sup> Giant Eagle incorporates its prior discussion of the Controlled Substances Act. *See* Doc. # 1923-1, Section I.A.



**A. HBC and GERX have always been in “full compliance” with the Controlled Substances Act and corresponding DEA security regulations**

Between 2009 and 2020, the DEA—with the participation of at least twelve different DEA Diversion Investigators—conducted seven in-depth, on-site investigations of HBC and GERX, and each time the result was the same: the DEA determined that Giant Eagle’s distribution operations were in “**full compliance**” with all DEA-promulgated recordkeeping and security regulations in Title 21 of the Code of Federal Regulations, *including* the requirement to maintain an effective SOM system to protect against diversion.<sup>5</sup> Giant Eagle has *never* been the subject of *any* administrative action, letter of admonishment, or other DEA reprimand. This unblemished compliance record over eleven years and at least seven investigations is truly exemplary, especially given testimony from the Counties’ DEA expert that over 50 percent of distributor investigations result in a letter of admonishment or other adverse action. SJ-Ex. 10 (Rafalski Tr. at 85:14-86:4).

**1. The DEA’s Investigation Process**

As explained by both Lewis Colosimo, the DEA Diversion Investigator who conducted investigations at both HBC and GERX, and the Counties’ DEA expert, James Rafalski, the DEA uses pre-registration and cyclic investigations to ensure that registrants comply with the DEA regulations governing the distribution of controlled substances—including the SOM regulation. SJ-Ex. 9 (Colosimo Tr. at 19:23-20:18, 24:14-25:1, 25:9-26:2, 38:3-39:15); SJ-Ex. 10 (Rafalski Tr. at 211:16-212:2) (“Q. And those routine investigations are meant to ensure compliance with the DEA’s regulations, is that fair? A. This is – yes, that is one of the aspects.”); *see also* SJ-Ex. 17 (DEA 30(b)(6) Tr. at 103:6-104:4, 129:20-130:12, 131:15-23) (DEA investigations ensure that

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<sup>5</sup> Prior to obtaining its Schedule III-V license in 2009, Giant Eagle was also the subject of DEA investigations with respect to its List I chemical distribution in 2002, 2004, and 2008, none of which found any violations. SJ-Ex. 3 (2011 ROI recounting List I investigations).

registrants “are doing what they’re saying” and are “actually detecting suspicious orders.”); SJ-Ex. 43 (DEA 30(b)(6) Tr. at 18:13-20, 24:12-18, 25:16-21).

After completing an investigation, the Diversion Investigator prepares a written Report of Investigation (“ROI”) that is ultimately approved by a Group Supervisor (“GS”), a rank obtained by Mr. Colosimo (over 30 years’ experience) but not Mr. Rafalski (a comparatively short 13-year tenure at the DEA). SJ-Ex. 9 (Colosimo Tr. at 14:2-5); SJ-Ex. 10 (Rafalski Tr. at 60:3-6). Any violation uncovered during an investigation must be discussed with management and documented on the ROI with a specific citation to the relevant CSA and/or CFR provision violated. *See* SJ-Ex. 9 (Colosimo Tr. at 26:24-27:4, 86:12-17); SJ-Ex. 43 (DEA 30(b)(6) Tr. at 20:2-22, 27:6-12); SJ-Ex. 8 at pg. 162 (“It is important for the Investigators to discuss all of the violations noted ... and to denote the appropriate section of the CFRs and/or the CSA which was violated.”).

## **2. The DEA repeatedly finds Giant Eagle in “full compliance” with all security regulations**

### **a) The 2009 pre-registration investigation of HBC**

Before Giant Eagle began distributing HCPs to itself in 2009, the DEA conducted an on-site “pre-registration investigation” of HBC. SJ-Ex. 1; SJ-Ex. 9 (Colosimo Tr. at 19:23-26:2, 38:3-9, 47:8-48:12). Giant Eagle provided the DEA with its written procedures pertaining to the CFR’s security requirements. SJ-Ex. 20 (Carlson Tr. at 86:8-25; 200:2-24). Diversion Investigator Colosimo had specific discussions with Giant Eagle’s management about the SOM regulation and Giant Eagle’s system to identify suspicious orders. SJ-Ex. 9 (Colosimo Tr. at 74:5-21); *id.* at 46:14-47:3, 49:17-25 (testifying that he reviews a registrant’s SOM system during his investigations).

After conducting a “thorough” investigation of HBC (SJ-Ex. 9 (Colosimo Tr. at 48:8-18)), the DEA *approved* Giant Eagle’s application and issued it the necessary license to distribute

Schedule III-V controlled substances. SJ-Ex. 1 at DEA-T1BCC-00001843-00001844 (Giant Eagle’s “[s]ecurity was operational and deemed adequate. ... With the approval of GS Kurt Dittmer, the application ... was approved.”). HBC thereafter only distributed one of the drugs at issue in CT3—Schedule III HCPs—and only to its in-store pharmacies.

**b) Repeated cyclic investigations by the DEA confirmed HBC’s “full compliance” with the CSA and corresponding regulations**

After approval, the registrant is subject to unannounced, in-depth, on-site investigations no less than every three years. SJ-Ex. 9 (Colosimo Tr. at 25:9-26:2, 45:11-46:1). As part of these “cyclic investigations,” the DEA Diversion Investigators review the registrant’s SOM system “in order to determine whether it complies with regulations.” SJ-Ex. 8 at pg. 160, § J.2. Mr. Rafalski agreed that a key component of every investigation is a determination by the DEA whether the registrant’s SOM system complies with the DEA’s security regulations. SJ-Ex. 10 (Rafalski Tr. at 71:16-23) (“Q. ... in both situations, you’re going to make sure that they either are going to have a SOM system that complies with the DEA regulations, or that they currently have and are operating a SOM system that complies with the DEA regulations[?]. A. Generally speaking, I agree with that, yes, sir.”). If, during a cyclic investigation, any question arises relating to a registrant’s compliance with any or all security regulations, the DEA would take administrative action to ensure compliance, ranging from a “formal administrative letter” to a license revocation, denial, or suspension. SJ-Ex. 9 (Colosimo Tr. at 59:16-60:9, 113:11-22, 119:2-15).

Remarkably, not one of the DEA’s cyclic investigations of Giant Eagle ever revealed any violations or issues with Giant Eagle’s overall security system, including its multi-layered SOM system. The DEA’s clear conclusion from these investigations, which it communicated repeatedly and directly to Giant Eagle’s management, was that Giant Eagle was in “full compliance” with all DEA recordkeeping and security regulations.

**2011 DEA Investigation (SJ-Ex. 3).** Over five days in May 2011, the DEA conducted a cyclic investigation of HBC, which included an investigation of its SOM system. After completing the investigation, the DEA Diversion Investigators concluded, with their Group Supervisor's approval, that there were "no discrepancies with respect to security." SJ-Ex. 3 at US-DEA-00033024; SJ-Ex. 9 (Colosimo Tr. at 100:3-12, 116:12-118:15).<sup>6</sup> As a result, the ROI notes that "this case is closed." SJ-Ex. 3 at US-DEA-00033024.<sup>7</sup>

**2013 DEA Investigation (SJ-Ex. 4).** The result of the DEA's 2013 cyclic investigation was the same: "no discrepancies with respect to recordkeeping or security." SJ-Ex. 4 at US-DEA-00030485; SJ-Ex. 9 (Colosimo Tr. at 120:10-21) (confirming that this included a review of HBC's SOM system). During the 2-day on-site investigation, the DEA Diversion Investigators and Giant Eagle personnel discussed Giant Eagle's SOM system in detail, including the critical fact that Giant Eagle only distributes controlled substances to its own corporate-owned and operated pharmacies. *See* SJ-Ex. 4 at US-DEA-00030487 ("Giant Eagle pharmacies are the subject firm's sole customer base.") and US-DEA-00030491-00030492. After describing a meeting between the DEA and Giant Eagle management, the ROI concludes: "During this meeting, investigators advised [Giant Eagle] that both recordkeeping *and security* are in *full compliance* with the requirement set forth in Title 21 Code of Federal Regulations." SJ-Ex. 4 at US-DEA-00030498 (emphasis added). As Diversion Investigator Colosimo confirmed, the DEA's determination of "full compliance" with Title 21 means full compliance with the SOM regulation at 21 C.F.R.

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<sup>6</sup> Simultaneously with the 2011 Schedule III-V investigation, the DEA also conducted a List I chemical investigation (over-the-counter pseudoephedrine and ephedrine) and concluded there were "no violations" of the CFR's security requirements. SJ-Ex. 2.

<sup>7</sup> The 2011 ROI indicated only "minor recordkeeping violations" that were "within the acceptable range" (SJ-Ex. 3 at US-DEA-00033024), and which were the result of a "computer software malfunction" unrelated to any issue in this case. SJ-Ex. 4 at US-DEA-00030487.

1301.74(b). SJ-Ex. 9 (Colosimo Tr. at 124:16-125:2). Accordingly, the DEA concluded: “this case is closed.” SJ-Ex. 4 at US-DEA-00030485.<sup>8</sup>

**2014 DEA Investigation (SJ-Ex. 5).** The result of the 2014 cyclic investigation was another clean report: “The investigation revealed no discrepancies with respect to recordkeeping or security.” SJ-Ex. 5 at US-DEA-00030618. And again, during a meeting with Giant Eagle management, “the investigators advised that both recordkeeping and security are in full compliance with the requirements set forth in Title 21 CFR.” SJ-Ex. 5 at US-DEA-00030631.<sup>9</sup> As before, the DEA concluded: “This case is closed.” SJ-Ex. 5 at US-DEA-00030618; US-DEA-00030631.

In 2016, Giant Eagle opened a new facility, known as GERX, to distribute Schedule II-V controlled substances.

**2016 DEA Pre-registration Investigation of GERX (SJ-Ex. 6).** Diversion Investigator Colosimo conducted a pre-registration investigation of the new GERX facility in 2016. SJ-Ex. 6; SJ-Ex. 9 (Colosimo Tr. at 87:16-88:4). The resulting ROI notes that “HBC has been the subject of three in-depth cyclic investigations [b]y the Pittsburgh D.O. ... [n]one of which resulted in any administrative actions.” SJ-Ex. 6 at DEA-T1BCC-00001846; SJ-Ex. 9 (Colosimo Tr. at 90:15-91:9, 93:3-7). The ROI acknowledges that because Giant Eagle self-distributes, it “will have access to customer information that will assist them in enacting the ‘Due Diligence’ actions,” which includes the ability to monitor all pharmacies for up-to-date licensing. SJ-Ex. 6 at DEA-

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<sup>8</sup> After advising Giant Eagle that it was in “full compliance” with the CFR, the 2013 ROI then goes on to note that DEA agents and a Giant Eagle employee discussed the possibility of adding an *additional* automated component to Giant Eagle’s existing SOM system, which Diversion Investigator Colosimo characterized as a “suggestion” from DEA. SJ-Ex. 9 (Colosimo Tr. at 124:1-15). Notably, Giant Eagle almost immediately implemented the DEA’s “suggestion” by adding a computerized threshold component to its SOM system. SJ-Ex. 9 (Colosimo Tr. at 126:3-127:20); SJ-Ex. 10 (Rafalski Tr. at 488:8-18) (admitting that Giant Eagle implemented automated computer threshold system approximately two months later).

<sup>9</sup> The 2014 ROI described the 2013 ROI as “resulting in no violations or discrepancies uncovered.” SJ-Ex. 5 at US-DEA-00030620-00030621

T1BCC-00001855-00001856; SJ-Ex. 9 (Colosimo Tr. at 106:4-108:9). The DEA approved GERX's application and issued the Schedule II license. SJ-Ex. 6.

**2017 DEA Investigation of GERX (SJ-Ex. 7).** The ROI prepared after the 2017 investigation of GERX *again* concluded: "This investigation revealed no discrepancies with respect to recordkeeping or security." SJ-Ex. 7 at US-DEA-00030402; SJ-Ex. 9 (Colosimo Tr. at 134:1-15) (this includes the SOM system). And yet again, the ROI states that during a DEA meeting with Giant Eagle management, "the investigators advised that both recordkeeping and security are in full compliance with the requirements set forth in Title 21 CFR," and, as such, "this case is closed." SJ-Ex. 7 at US-DEA-00030417-00030418.<sup>10</sup>

Given Giant Eagle's unblemished record of "full compliance," it is unsurprising that the DEA *never* issued an order to show cause, never issued any citations or letters of admonition, and never pursued any adverse actions against HBC. SJ-Ex. 10 (Rafalski Tr. at 454:5-19).<sup>11</sup>

**B. Giant Eagle's pharmacies likewise have always been in full compliance with the CSA and Ohio BOP regulations**

As with distribution, the undisputed evidence shows that Giant Eagle, at all times, complied with the DEA's and Ohio Board of Pharmacy's *dispensing* regulations.

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<sup>10</sup> Discovery of the DEA ended before Giant Eagle was able to obtain a copy of the 2020 ROI; however, the DEA's 2020 investigation of GERX is evidenced by the facility's sign-in sheet, attached as SJ-Ex. 46, and there is no evidence suggesting that investigation did not result in the same "full compliance" determination as the prior six investigations.

<sup>11</sup> The Giant Eagle employees who interacted with the DEA during these investigations confirmed in consistent and un rebutted testimony that Giant Eagle fully cooperated with the DEA at all times, provided the DEA with everything it needed, and the DEA, in turn, *never* raised any issues or concerns with Giant Eagle's compliance with the CSA. See SJ-Ex. 19 (Giant Eagle 30(b)(6) Tr. at 286:14-19) ("To your knowledge, has there ever been a problem raised by the DEA or the Ohio Board of Pharmacy related to any of the Giant Eagle pharmacies in these two jurisdictions? ... A. Not to my knowledge, no."); SJ-Ex. 21 (Chunderlik Tr. at 259:19-23) (Q. Did the DEA ever tell HBC that they were not meeting the security requirements under the regulations, under the regulation related to the Controlled Substances Act? A. Not that I know of, no."); SJ-Ex. 20 (Carlson Tr. at 222:24-223:16) ("Q. At any time, did the DEA ever advise HBC that there was anything lacking in their control system? ... A. There was nothing pointed out within our security measures that didn't meet the requirements."); SJ-Ex. 18 (Durr Tr. at 171:16-22) ("Q. In working with the DEA and during their multiple inspections before, during, and after the HBC narcotics room was set up or any of their surprise audits, did they at any time ever give you any indication that HBC was not in full compliance with the security requirement? A. No, they did not.").

## 1. Ohio Board of Pharmacy Inspections

Every Giant Eagle pharmacy in Lake County and Trumbull County was subject to frequent inspections by the Ohio BOP, the agency responsible for ensuring that pharmacies dispense controlled substances in compliance with all applicable state and federal laws. O.A.C. § 4729-9 *et. seq.*; SJ-Ex. 12 (Catizone Tr. at 318:22-319:2). Through 2019, the Ohio BOP conducted at least 92 inspections of the Giant Eagle pharmacies in the two Counties. *See* SJ-Ex. 11. As part of these inspections, the Ohio BOP examines and evaluates the pharmacy's dispensing systems and operations to ensure compliance with state and federal laws. SJ-Ex. 12 (Catizone Tr. at 320:1-321:1, 439:21-440:3, 464:8-465:7). With the exception of a few minor issues — which Giant Eagle quickly resolved — the Ohio BOP consistently concluded that Giant Eagle pharmacies were operating lawfully in compliance with all relevant law and regulations. SJ-Ex. 11. The Ohio BOP never identified Giant Eagle's pharmacies in the two counties as possible diversion sites. *See e.g.* SJ-Ex. 13 (Edwards Tr. at 157:5-19, 166:9-167:6, 173:20-174:6); SJ-Ex. 39 (Giant Eagle 30(b)(6) Tr. at 191:2-9) (“Q. And for that matter, in all of the contacts with law enforcement and Board of Pharmacy, police that we’ve seen, did anybody from Lake or Trumbull County law enforcement or otherwise ever complain about Giant Eagle’s dispensing practices? ... A. No, never.”).<sup>12</sup>

## 2. Ohio BOP agents who inspected Giant Eagle pharmacies confirmed its near-perfect record of compliance and cooperation

The Ohio BOP agents who actually interacted with and inspected Giant Eagle pharmacies in Lake and Trumbull Counties (unlike the Counties’ hired litigation experts) confirmed that the

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<sup>12</sup> *See also* SJ-Ex. 19 (Giant Eagle 30(b)(6) Tr. at 97:9-22) (“Q. The software dispensing system that Giant Eagle used, was it subjected to repeated Ohio Board of Pharmacy inspections and audits? A. Yes. Absolutely. Continual check-ins on it. And certainly as we rolled out new modules or improvements on the system, that was -- at the next inspection, was highlighted or looked at from the board, certainly. Q. To your knowledge, did the Board of Pharmacy ever criticize or suggest to Giant Eagle that it should -- it needed better dispensing software than what it was using? A. Never.”).

pharmacies complied with Ohio and DEA security requirements and dispensing regulations and operated lawfully at all times.

- Special Agent William “Trey” Edwards, formerly of the Lake County Narcotics Agency and currently an Ohio BOP agent, inspected Giant Eagle pharmacies 25 times between 2009 and 2019, and testified that Giant Eagle performed its duties lawfully at all times, cooperated with law enforcement, identified potential diversion, and provided adequate responses to any suggested improvements at the pharmacies. SJ-Ex. 13 at 192:3-196:17. The Giant Eagle pharmacy inspections were “favorable,” and the pharmacies were doing what they were supposed to do under the Board’s rules. SJ-Ex. 13 at 147:13-18.
- Agent George Pavlich, who worked as an agent for the Ohio BOP until 2012 and inspected Giant Eagle pharmacies 21 times, testified that they properly processed prescriptions, operated lawfully at all times, and met the security requirements imposed by Ohio law. SJ-Ex. 14 at 166:1-171:7.
- Agent William DiFrangia, Ohio BOP Field Agent/Compliance, testified that at all times Giant Eagle operated lawfully, and complied with the security regulations by, among other things, providing Ohio BOP agents with leads relating to possible diversion. SJ-Ex. 15 at 65:23-66:6, 69:2-10, 163:3-165:11, 167:7-18.
- Detective Damian Blakely of the Lake County Narcotics Agency, Prescription Task Force, testified that he never even investigated Giant Eagle because he never saw any evidence suggesting that it was engaged in diversion. SJ-Ex. 16 at 62:15-20.

**C. Giant Eagle never showed any indicia of a “bad distributor” or “bad pharmacy” engaged in possible diversion**

Putting aside its uniformly clean federal and state inspections, Giant Eagle never exhibited any of the hallmarks of a “bad distributor” or “bad pharmacy” that likely engaged in opioid diversion. *See* SJ-Ex. 17 (DEA 30(b)(6) Tr. at 480:24-481:1) (“DEA has acknowledged ... that no chain pharmacies were rogue pharmacies.”).

**1. Giant Eagle self-distributed at all times and never to third parties**

As a self-distributor, Giant Eagle is very different than a large wholesaler distributor who ships multiple types, brands, and strengths of controlled substances to thousands of unaffiliated third-party pharmacies throughout the country. Giant Eagle operates within an entirely closed system and maintains possession and control over all products until they are actually dispensed to



customers. *See, e.g.*, SJ-Ex. 17 (DEA 30(b)(6) Tr. at 1175:14-1176:14). By definition then, Giant Eagle does not merely “know its customer” as the DEA requires for all distributors; rather, Giant Eagle knows everything about its customers because Giant Eagle *is its own* customer and, therefore, can quickly determine if a potentially “suspicious” order is not actually suspicious. Doc. # 3327 at ¶ 102 (Defendants “must know their customers and the communities they serve.”); SJ-Ex. 9 (Colosimo Tr. at 40:8-41:11) (self-distributor status is a factor in the “know your customer” analysis); *id.* at 107:9-16.

Along these lines, Giant Eagle hires, trains, and manages its pharmacists and, at all times, knows their qualifications, credentials, and licensing status. It also monitors and fully understands the specific circumstances and markets that may affect the number of controlled and non-controlled prescriptions filled by each pharmacy. *See* SJ-Ex. 9 (Colosimo Tr. at 107:17-108:9) (self-distributors can monitor all pharmacies for up-to-date licensing). Additionally, Giant Eagle’s corporate headquarters oversees its distribution and pharmacy operations, which enables Giant Eagle to quickly and efficiently perform due diligence to clear orders that may appear suspicious. *Id.* at 106:4-19 (self-distributors like Giant Eagle “will have access to customer information that will assist them in following the ‘due diligence’ actions.”). *See also* SJ-Ex. 21 (Chunderlik Tr. at 250:4-22) (Giant Eagle had tools in place to monitor both purchases and dispensing at the pharmacy level and required extensive auditing of retail pharmacies); SJ-Ex. 39 (Giant Eagle 30(b)(6) Tr. at 204:14-205:5) (it was “absolutely” a “regular practice of the Giant Eagle corporate compliance department to respond” to pharmacists’ due diligence investigations and help resolve those issues as “normal course of business and oversight”).

**2. Giant Eagle's opioid dispensing decreased in the two Counties even while DEA quotas increased**

Beginning in 2012, Giant Eagle's dispensing of HCPs began to *decrease* significantly even as national demand and DEA quotas for opioids increased dramatically. SJ-Ex. 37; Doc. # 3327 at ¶ 97 (acknowledging limits set by DEA quotas).<sup>13</sup> Similarly, Giant Eagle's dispensing of oxycodone decreased or stayed relatively flat during the same time period that DEA quotas increased significantly. SJ-Ex. 37. That Giant Eagle was dispensing less of these opioids while our nation's pharmacies were dispensing more of them pursuant to increasing DEA quotas confirms that Giant Eagle was not a significant source of diversion in Lake and Trumbull Counties, and that Giant Eagle's pharmacists were complying with their corresponding obligation.

**3. Giant Eagle's dispensing ratio of controlled compared to non-controlled substances was far below the DEA's threshold for suspicion requiring possible investigation**

Another indicia recognized by the DEA (and acknowledged by the Counties) as indicating a potentially "bad pharmacy" is when the pharmacy dispenses controlled substances at a ratio compared to non-controlled substances exceeding 20 percent. SJ-Ex. 10 (Rafalski Tr. at 123-24); Doc. # 3327 at ¶ 131. Giant Eagle's ratio does not even come close. Between January 2006 and November 2019, Giant Eagle pharmacies in the two Counties averaged a dispensing ratio of 9.8% controlled to 90.2% non-controlled, SJ-Ex. 31, which is less than *half* of the 20%/80% ratio that the DEA and the Counties' DEA expert have said is *common* even among "legitimate pharmacies." SJ-Ex. 23 (DEA 30(b)(6) Tr. at 260:1-22); SJ-Ex. 10 (Rafalski Tr. at 126:13-20) (twenty percent controlled is around where he would get "concerned"); SJ-Ex. 24 (Rannazzisi Tr. at 453:16-454:8) (explaining that its "a red flag when a pharmacy is ordering, you know, 40, 50 percent of their drugs as controlled substances"). As Mr. Rafalski admitted when presented with Giant Eagle's

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<sup>13</sup> SJ-Ex. 26; SJ-Ex. 25 (DEA 30(b)(6) Tr. at 97:22-98:4) (confirming aggregate production quotas from 2009-2018).

store-by-store data: “I don’t see one here that is alarming.” SJ-Ex. 10 at 134:10; SJ-Ex. 12 (Catizone Tr. at 424:25-425:5) (ignoring controlled vs. non-controlled ratios entirely).

**4. Compared to its in-county peers, Giant Eagle dispensed opioids at much lower MME levels per transaction, dosage unit, and day**

Other undisputed facts about Giant Eagle’s dispensing in Lake and Trumbull Counties precludes any inference that Giant Eagle’s pharmacies were a source of diversion.

- [REDACTED]
  - [REDACTED] Doc. # 3327 at ¶ 68 (alleging that “[a]ccording to the CDC, doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day ....”).
  - [REDACTED]
  - [REDACTED]
- Notably, Mr. Rafalski agreed that even dispensing a “couple hundred dosage units a month”—[REDACTED] “shouldn’t raise [an] eyebrow,” and “would not be a red flag.” SJ-Ex. 10 at 149:15-150:1. Indeed, Mr. Rafalski agreed that a pharmacy “doesn’t need to do any further due diligence” when it is dispensing “a [couple hundred] dosage units a month.” *Id.* at 149:15-150:1. Mr. Rafalski testified that he “wouldn’t rush” to investigate Giant Eagle based on its dispensing data. *Id.* at 155:10-20.
- Giant Eagle has deactivated (refused to fill) prescriptions at a rate of 0.51%, which aligns almost perfectly with the DEA’s testimony to the United States House of Representatives that 99.5% of prescribers are not over-prescribing. SJ-Ex. 30.<sup>14</sup>

<sup>14</sup> See *Challenges and Solutions in the Opioid Crisis: Hearing before the H. Comm. on the Judiciary*, 115th Cong. 32 (2018) (statement of Robert W. Patterson, Acting Administrator, DEA) (“But I go back to the fact that I look at the vast majority of doctors: 99.99 percent are all trying to do right by their patients.”); *Examining the Growing Problems of Prescription Drug and Heroin Abuse: Hearing before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy & Commerce*, 113th Cong. 76 (2014) (statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, DEA) (“I think that if you are talking about 99.5 percent of the prescribers, no, they are not overprescribing, but our focus is in rogue pain clinics and rogue doctors who are overprescribing.”); see also SJ-Ex. 17 (DEA 30(b)(6) Tr. at 401:5-403:19 at 438:7-439:11) (confirming both statements).

**5. Cash payments for opioid prescriptions at Giant Eagle were consistent with cash payments for all drugs**

Another potential indicia of diversion recognized by the DEA and acknowledged by the Counties is when an excessive amount of a pharmacy's opioid prescriptions are paid for entirely in cash despite the availability of insurance. SJ-Ex. 10 (Rafalski Tr. at 124:1-2) ("I would look at cash and noncash payments."); Doc. # 3327 at ¶ 109. The Counties' DEA expert, Mr. Rafalski, testified that "lower than 20 percent" was "the usual percentage that a good pharmacy would have of cash transactions for controlled substances." SJ-Ex. 10 at 132:16-23. In Giant Eagle's case, the proportion of dispensed opioid prescriptions paid for in cash was 5.2%, which aligns perfectly with the *overall* rate of cash payments for *all* prescriptions. SJ-Ex. 38.<sup>15</sup> Put another way, 95% of the opioid prescriptions filled at Giant Eagle's pharmacies were approved and paid for by health insurance plans, and the remaining 5% were paid for in cash, much lower than the 20% expected.

**D. Giant Eagle assisted law enforcement in preventing diversion, which belies any contention that Giant Eagle intentionally and/or unlawfully contributed to the opioid epidemic in Lake and Trumbull Counties**

Giant Eagle did not just comply with all laws and regulations designed to prevent diversion—it *actively assisted* law enforcement in their efforts to put an end to diversion. The Ohio BOP agents testified that Giant Eagle was "cooperative and proactive in attempting to avoid diversion and investigate and prosecute diversion." SJ-Ex. 15 (DiFrangia Tr. at 68:9-18, 65:23-66:6); *see also* SJ-Ex. 14 (Pavlich Tr. at 171:4-7); SJ-Ex. 16 (Blakeley Tr. at 58:7-14). Giant Eagle contacted law enforcement "countless amounts of times when [its] pharmacists have – have found an illegal prescription or fraudulent prescription." SJ-Ex. 15 (DiFrangia Tr. at 67:11-68:7). Giant Eagle pharmacists contacted Lake County detectives *before* filling prescriptions that the

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<sup>15</sup> *Number of Retail Prescription Drugs Filled at Pharmacies by Payer, Timeframe: 2019*, KFF, <https://www.kff.org/health-costs/state-indicator/total-retail-rx-drugs/> (last visited July 9, 2021).

pharmacists considered to be suspicious, and such reports led to arrests and criminal charges. SJ-Ex. 16 (Blakely Tr. at 106:3-24). Ultimately, as Detective Blakely testified, Giant Eagle pharmacists *stopped diversion in its tracks* by refusing to fill suspected bad prescriptions and reporting them to the police. SJ-Ex. 16 (Blakely Tr. at 248:11-249:24); *id.* at 76:22-77:2, 111:2-112:12, 230:13-233:4 (detailing examples of Giant Eagle pharmacists reporting suspicious prescriptions to police and cooperating with investigations).<sup>16</sup>

At the corporate level, Giant Eagle never advertised or promoted opioids, and it never implemented any other strategy or approach designed to increase opioid sales. SJ-Ex. 27 (Tommasi Tr. at 48:11-18). In 2013, Giant Eagle hired Richard Shaheen, a former agent and pharmacy diversion investigator for the Pennsylvania Office of the Attorney General for 26 years, to oversee pharmacy investigations and security. SJ-Ex. 28 (Shaheen Tr. at 17:16-23:19).<sup>17</sup> Giant Eagle also employs Pharmacy District Leaders (PDLs), who exercise close managerial oversight of the pharmacies, inspecting all pharmacy operations, enforcing company-wide policies and procedures, performing quarterly internal audits, and ensuring compliance with state and federal regulations. SJ-Ex. 19 (Giant Eagle 30(b)(6) Tr. at 289:9-290:19). PDLs work with law enforcement and the Boards of Pharmacy to help deter diversion and prosecute criminals. *Id.*; *see also* SJ-Ex. 21 (Chunderlik Tr. at 268:15-270:11).

Giant Eagle pharmacists employ extra internal controls not required by the DEA or Ohio BOP, including double-counting; back-counting (total number of pills left in inventory equals prior

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<sup>16</sup> One rogue prescriber who flooded Lake and Trumbull Counties with over 15,000 illegitimate opioid prescriptions specifically instructed his patients *not to* try to fill their scripts at the Giant Eagle pharmacy closest to his practice because Giant Eagle would not fill them. SJ-Ex. 14 (Pavlich Tr. at 187:7-18); *id.* at 189:3-19 (“It was a Rite-Aid, and there was a Giant Eagle up the street... they weren’t really filling [Franklin prescriptions]. I mean, they had a couple in there, a few, but they caught on right away.”); *id.* at 191:19-192:19 (“Why do you think the patients drove, you know, 50 miles down the road to go to Overholt? Because they weren’t getting it dispensed [by Giant Eagle and Rite Aid]. They were getting it at Overholt.”); SJ-Ex. 10 (Rafalski Tr. at 156:18-157:13) (admitting he was unaware of, and did not consider, this fact in his report).

<sup>17</sup> Mr. Shaheen worked and cooperated with Diversion Investigator Colosimo. SJ-Ex. 9 (Colosimo Tr. at 29:1-33:20).

count minus current prescription being filled); perpetual inventory (inventory updated and checked after every transaction, rather than every 2 years as required by DEA regulations); monthly controlled substances inventory counts; and random inventory checks. SJ-Ex. 19 (Giant Eagle 30(b)(6) Tr. at 269:15-296:25).<sup>18</sup>

## II. ANALYSIS

### A. Giant Eagle is entitled to “safe harbor” immunity from liability for absolute public nuisance because the evidence shows that at all times, Giant Eagle was in full compliance with its regulatory obligations

The Court’s prior rulings in this MDL establish that “safe harbor” immunity is available to defendants who “perform in accordance with their applicable licensing regulatory obligations.” Doc. # 3403 at 29-30 (Court order re Pharmacy Defendants’ Motion to Dismiss); Doc. # 3177 at 45-47. *See also City of Cleveland v. Ameritrust Mortgage Securities, Inc.*, 621 F. Supp. 2d 513, 528 (N.D. Ohio 2009) (conduct that complies with regulations cannot be a nuisance); *Hager v. Waste Techs. Indus.*, 2002-Ohio-3466, 2002 Ohio App. LEXIS 3558 (Ohio Ct. App. 2002) (reaffirming “general rule” that “conduct which is fully authorized by statute or administrative regulation is not actionable as a public nuisance” and holding that “[s]ince [Defendant’s] waste incineration facility operates under sanction of law, based on that fact alone, it cannot be a common law public nuisance.”) This is consistent with Comment *f* to the Restatement (Second) of Torts § 821B (titled “Effect of Compliance”), which provides that “[a]lthough it would be a nuisance at common law, conduct that is fully authorized by statute, ordinance or administrative regulation does not subject the actor to tort liability.”<sup>19</sup> Giant Eagle’s record of full compliance entitles it to safe harbor immunity from public nuisance liability.

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<sup>18</sup> Giant Eagle incorporates by reference the fact section of its Motion for Summary Judgment in Track One, which contains additional details about Giant Eagle’s extensive controls at all levels. Doc. # 1923, Section B.

<sup>19</sup> For purposes of this Motion only, and without waiver of any rights, Giant Eagle refers to and accepts the Court’s prior descriptions of the public nuisance claim at issue in Track Three.

### 1. Giant Eagle meets all requirements for “safe harbor” immunity

Giant Eagle at all times performed “in accordance with [its] applicable licensing regulatory obligations.” Doc. # 3403 at 29-30. The DEA repeatedly inspected Giant Eagle’s facilities and operations and concluded time and time again that Giant Eagle was in “**full compliance**” with its recordkeeping and security obligations under 21 C.F.R. § 1301.74(b). *See* SJ-Exs. 1-7. Giant Eagle *never* received any letter of admonition or other reprimand from the DEA relating to its security systems.<sup>20</sup> *Compare* to Doc. # 3327 at ¶ 138 (emphasizing DEA’s “long history of enforcement actions” against Big Three distributors as evidence of their “compliance failures” but not a single reference to any such failure by Giant Eagle).

Giant Eagle’s unblemished record with the DEA is both exemplary and rare. According to the Counties’ DEA expert, 50% of all DEA distributor investigations find at least “some kind of violation.” SJ-Ex. 10 (Rafalski Tr. at 85:14-86:4). Yet Giant Eagle had no violations over the course of eleven years and at least seven investigations conducted by at least twelve different agents. The same is true about Giant Eagle’s dispensing activities—the Ohio BOP conducted at least 92 inspections of Giant Eagle pharmacies in the Counties and repeatedly found Giant Eagle in compliance with applicable security regulations. SJ-Ex. 11. If any registrant in Ohio is entitled to safe harbor immunity, it is Giant Eagle.<sup>21</sup>

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<sup>20</sup> As Diversion Investigator Colosimo testified, had Giant Eagle been in violation of the security requirements, such violation would have been documented in the ROIs. SJ-Ex. 9 (Colosimo Tr. at 86:12-87:7, 89:1-10); *see also* SJ-Ex. 10 (Rafalski Tr. at 77:7-20) (a “letter of admonition” is the “lowest formal level” of action the DEA would take if a registrant was not in compliance).

<sup>21</sup> Even if Plaintiffs could prove some random technical violation of DEA or Ohio BOP regulations at some point in time (which they cannot, aside from minor incidents and thefts that occur from time-to-time in all pharmacies and are self-reported to responsible authorities), this would not be sufficient to establish the *unlawful* conduct necessary for a public nuisance claim or otherwise negate the application of “safe harbor” immunity. The CFR and similar Ohio regulations require “substantial compliance,” not “strict compliance.” 21 C.F.R. § 1301.71(b); OAC-4729-9-05; SJ-Ex. 9 (Colosimo Tr. at 39:3-15); SJ-Ex. 10 (Rafalski Tr. at 89:8-90:9) (compliance does not have to be “perfect” and “substantial is more than just average or trying. I think it shows a high-level attempt to be in compliance.”); SJ-Ex. 17 (DEA 30(b)(6) Tr. at 395:10–396:18) (substantial compliance is sufficient).



**2. There is no dispute that Giant Eagle was entitled to rely on the DEA's and Ohio BOP's determination of "full compliance" with all applicable security regulations**

As documented in the ROIs, after completing their multiple investigations, the DEA Diversion Investigators specifically informed Giant Eagle's management that HBC and GERX were in "full compliance" with the CFR's security regulations. SJ-Exs. 1-7. Both Diversion Investigator Colosimo and Mr. Rafalski endorsed the unremarkable proposition that registrants like Giant Eagle *are entitled and expected to* rely upon the favorable results of their DEA's investigations in determining whether their security systems, including their SOMS, are "at least adequate, if not more than adequate, under the CFR and similar Ohio regulations." SJ-Ex. 9 (Colosimo Tr. at 86:18-87:7); SJ-Ex. 10 (Rafalski Tr. at 82:2-11) ("Q. ... You're a DEA investigator whose job it is to enforce those regulations. Nobody knows those regulations, presumably, when you're on the job, any better than you, and you're coming into a registrant and you're telling them that they're okay, shouldn't they be able to rely on that? ... A. As I answered earlier, I generally agree with that."). Giant Eagle did, in fact, justifiably rely upon these favorable determinations in designing, operating, maintaining, *and continually improving* its security measures. *See, e.g.*, SJ-Ex. 20 (Carlson Tr. at 86:8-25; 200:2-24) ("[The DEA] looked at all of our security features related to [the CSA], looked at all of our processes. Our security, according to them, fit all requirements, all the needed necessary steps. We were acting upon that.").<sup>22</sup>

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<sup>22</sup> *See also* SJ-Ex. 22 (Mollica Tr. at 60:3-61:3) ("A. We supported pharmacists' right to make professional judgments as to what was proper and improper in terms of dispensing, made sure the pharmacists knew that they had the right, final right of decision making when it came to dispensing. We had our controlled substance procedures that we made sure was distributed. We had audit procedures that were done quarterly and documented .... We had practices in terms of document retention and what needed to be done in terms of proper ordering, training, training on -- we had manuals and references regarding not only the DEA, but Pharmacy Act and fraud, waste and abuse policies, CBTs [computer based training], annual meetings with a lot of discussions of what the obligation of pharmacists were and helped in any way. We've had DEA inspections which were never -- never got any feedback that we weren't doing anything other than what was required from us from a legal perspective.").



Giant Eagle's reliance on the repeated determinations by multiple governmental agencies, acting through multiple experienced agents, that Giant Eagle was in "full compliance" with all regulations underscores why it is critical that registrants with an untarnished regulatory record like Giant Eagle be afforded "safe harbor" immunity. Had the DEA found any violations during their many investigations of HBC or GERX, Giant Eagle could have (and certainly would have) promptly taken corrective action. Thus, even if Mr. Rafalski's well-paid-for Monday-morning-quarterbacking of Giant Eagle's SOM system had validity (and it does not), Giant Eagle reasonably relied to its detriment on the DEA's repeated assurances that its security systems were in "full compliance" with the CFR's security regulations. Any notion that Giant Eagle should have ignored the DEA's explicit determinations of "full compliance" and, instead, endeavored to meet the amorphous expectations of a *different* DEA employee working as an expert witness over a decade later is both unreasonable and impossible.

The law recognizes this basic principle. Under the Restatement (Second) of Torts, it is proper to consider an actor's "reliance on legislation" as a defense, particularly where, like here, there is an "established[,] comprehensive set of legislative acts or administrative regulations governing the details of a particular kind of conduct" and there are administrative agencies (the DEA and Ohio BOP) that are "capable of handling [the problem] appropriately." Restat. (Second) Torts § 821B, cmt. f (courts are appropriately "slow to declare an activity to be a public nuisance if it complies with the regulations").

This reliance defense applies with even greater force where the registrant has fully disclosed its operations to regulatory authorities, and those authorities, in response, affirmatively declare such operations to be fully compliant. In *S. Appalachian Mt. Stewards v. Red River Coal Co.*, for example, the court held that Red River, a mining company, could not be held civilly liable

for discharging pollutants in violation of the Clean Water Act where it had fully disclosed the discharges to the regulatory agency and the agency specifically chose not to limit the company's discharges in its operating permit. 420 F. Supp. 3d 481, 496 (W.D. Va. 2019) *aff'd* 992 F. 3d 306 (4<sup>th</sup> Cir. 2020). As the court explained:

The undisputed evidence demonstrates that Red River has done exactly what [the agency] has told it to do. Red River should be able to rely upon the clear directives of its regulators without being subjected to liability. ... By being completely forthcoming with [the agency] and complying with the express terms of its Permit, Red River has met its obligations under [the law] and is entitled to rely on the permit shield.

*Id.* at 497. *Cf. NLRB v. Bell Aerospace Co. Div. of Textron, Inc.*, 416 U.S. 267, 295 (1974) (“this is not a case in which some new liability is sought to be imposed on individuals for past actions which were taken in good faith reliance on [agency] pronouncements.”).<sup>23</sup>

This conclusion applies equally here. The DEA and Ohio BOP are perfectly “capable of handling” the question of whether Giant Eagle complied with the applicable anti-diversion and other regulations, and they definitively answered that question in the affirmative every time. Put simply, Giant Eagle did exactly what it was *supposed to do* and it did exactly what the DEA and Ohio BOP “told it to do.” *Red River*, 420 F. Supp. 3d at 497. There is no legal or factual basis for

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<sup>23</sup> The U.S. Supreme Court has long recognized reliance on governmental assurances as a defense in the criminal arena, and there is no reason that same principle should not apply here. *See U.S. v. Pennsylvania Industrial Chemical Corp.*, 411 U.S. 655, 675 (1973) (defendant is permitted to present evidence that it was “affirmatively misled by the responsible administrative agency into believing the law did not apply in this situation” and “there can be no question that [defendant] had a right to look to the Corps of Engineers’ regulations for guidance.”) (cleaned up); *U.S. v. Laub*, 385 U.S. 475, 487 (1967) (“Ordinarily, citizens may not be punished for actions undertaken in good faith reliance upon authoritative assurance that punishment will not attach.”); *Raley v. Ohio*, 360 U.S. 423, 425-26 (1959) (Due Process Clause prohibits “the most indefensible sort of entrapment by the State – convicting a citizen for exercising a privilege which the State had clearly told him was available to him.”); *id.* at 438-39 (defendants could not be held criminally liable for invoking Fifth Amendment privilege against self-incrimination where a person who “clearly appeared to be the agent of the State in a position to give ... assurances” did, in fact, apprise the defendants through words and behavior that their invocation of the privilege was appropriate).

a jury to overrule the favorable on-the-ground determinations made by these agencies and impose a post-hoc finding that Giant Eagle *actually* was unknowingly violating the law the whole time.<sup>24</sup>

### **3. The Counties’ attempt to retroactively regulate Giant Eagle violates Giant Eagle’s due process rights**

Relatedly, imposing civil liability on these facts would violate Giant Eagle’s due process rights. “A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required. ... This requirement of clarity in regulation is essential to protections provided by the Due Process Clause of the Fifth Amendment.” *FCC v. Fox TV Stations, Inc.*, 567 U.S. 239, 253 (2012) (“All persons are entitled to be informed as to what the State commands or forbids.”) (cleaned up). Accordingly, “a conviction or punishment fails to comply with due process if the statute or regulation under which it is obtained fails to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement.” *Id.* at 246 (cleaned up) (“regulated parties should know what is required of them so they may act accordingly” and, to that end, “precision and guidance are necessary so that those enforcing the law do not act in an arbitrary or discriminatory way.”).

The imposition of common law tort liability is an exercise of state power that must comply with the “fair notice” requirements of due process—in other words, the Counties cannot use a tort lawsuit to either change the regulations under which Giant Eagle operated or overturn its record of “full compliance” with those regulations. *Cipollone v. Liggett Group*, 505 U.S. 504, 521 (1992)

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<sup>24</sup> Perhaps the most vivid illustration of the reasonableness of Giant Eagle’s reliance comes from a Giant Eagle pharmacist’s written recounting of a meeting with a DEA agent who was investigating a complaint *by a doctor* that Giant Eagle was refusing to fill opioid prescriptions that indicated potential diversion. SJ-Ex. 40 (Aug. 17, 2018 Email to Michael Chappell and others from Kelly Chappell, Re: “Kelly Chappell - DEA Investigator Meeting”, GE\_TL00002048-00002050). The pharmacist explained in detail Giant Eagle’s procedures for vetting controlled substance prescriptions. Then, at the end of that meeting, the Giant Eagle pharmacist asked what else, if anything, the DEA needed, and the DEA advised: “keep doing what you are doing. Keep fighting the good fight.” *Id.* at 3.

(citing *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)) (“state regulation can be as effectively exerted through an award of damages as through some form of preventative relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.”).<sup>25</sup>

The Counties ignore these principles. They attempt to use a common law tort action to retroactively declare that *despite* Giant Eagle’s record of “all clean inspections” (*see* SJ-Ex. 10 (Rafalski Tr. at 448:9-18)), in their eyes Giant Eagle *actually* was violating the CSA, CFR, and Ohio regulations the whole time. Giant Eagle did not have “fair notice” that the DEA’s repeated determinations of “full compliance” with all DEA regulations (or the Ohio BOP’s similar conclusions) would or could be retroactively changed by unknown plaintiffs ten years later asserting a common law nuisance claim. *See also United States v. Hoescht Celanese Corp.*, 128 F.3d 216, 225-226 (4<sup>th</sup> Cir. 1997) (“in addressing whether a party has received fair notice, we look at the facts as they appear to the party entitled to the notice, not to the agency.”).<sup>26</sup>

The Counties’ attempt to retroactively re-regulate Giant Eagle usurps the role of the regulator and encourages the standardless, arbitrary, and contradictory enforcement of comprehensive regulations by private litigants—the Counties just want to change the outcome of Giant Eagle’s investigations from a perfect “A” to an “F.” *See* SJ-Ex. 10 (Rafalski Tr. at 76:9-12) (describing DEA investigations as “pass or fail”). It also severely prejudices Giant Eagle, which would have improved its systems had the actual agencies “capable of handling it” identified any problems (or even just made “suggestions,” as when the DEA suggested adding automation to

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<sup>25</sup> *Honda Motor Co. v. Oberg*, 512 U.S. 415, 434-35 (1994) (“A decision to punish a tortfeasor by means of an extraction of exemplary damages is an exercise of state power that must comply with the Due Process Clause of the Fourteenth Amendment.”).

<sup>26</sup> There is no evidence that prior to filing their complaints, the Counties or their agents ever once complained that Giant Eagle was somehow violating the law.

Giant Eagle's SOM system and Giant Eagle immediately did so). *See Christopher v. Smithkline Beechum Corp.*, 567 U.S. 142, 158 (2012) (holding that defendant was not liable in private civil suit premised on alleged regulatory violation because defendant did not have fair notice of alleged violation where the agency "never initiated any enforcement actions ... or otherwise suggested that it thought the industry was acting unlawfully" and further noting that "the potential for unfair surprise is acute" where there is a "very lengthy period of conspicuous [agency] inaction.").

What makes the Counties' regulation-by-litigation approach even more unfounded is that Mr. Rafalski offers his cryptic conclusion that Giant Eagle did not maintain effective controls without explaining *why* he "disagrees" with the consistent findings of at least twelve experienced DEA Diversion Investigators who actually inspected Giant Eagle's facilities and systems, or how those agents could have gotten it so wrong over so many years. SJ-Ex. 10 at 461:17-462:4. In fact, unlike his former colleagues at the DEA, Mr. Rafalski never inspected any Giant Eagle facility or even looked at a single inspection report prior to forming his conclusion that Giant Eagle did not maintain effective controls. *Id.* at 462:5-12 ("Q. ... you haven't taken the time to review any of these inspection reports, correct? ... A. That's correct."); *id.* at 75:9-19 (prior ROIs are available to DEA inspectors); *id.* at 440:1-9 (never inspected HBC or GERX)). Mr. Rafalski also never went to any relevant Giant Eagle pharmacy despite testifying that the first thing a Diversion Investigator does is actually observe the pharmacy. *Id.* at 145:10-21, 239:3-6. Mr. Rafalski thus did not even do the most basic things that every DEA Diversion Investigator must do when performing investigations. SJ-Ex. 9 (Colosimo Tr. at 25:2-26:2); SJ-Ex. 8 at 158 (first step under "preparation" for cyclic investigation is "Review DEA files ... for mention of the firm to determine history and whether any complaints have been submitted concerning the firm or its products.")). His unfounded conclusions would never pass muster at the DEA, and certainly cannot be the basis

for overturning the “full compliance” determinations made by agents who actually performed in-depth investigations of Giant Eagle’s security measures.

The DEA investigation reports conclude, in each instance, “case closed,” which, as Mr. Rafalski explained, means “the matter has had a final resolution.” SJ-Ex. 10 at 465:7-19. It would make a mockery of the “fair notice” requirement to allow the Counties to overturn the DEA’s repeated “full compliance” determinations in a tort lawsuit based on the private litigation opinion of a former DEA employee who never stepped foot in a Giant Eagle facility and has no unique (and arguably fewer) qualifications that set him apart from his former colleagues and superiors. *Id.* at 64:18-66:23.

#### **4. The Counties have no evidence that Giant Eagle acted unlawfully**

Nothing in the record suggests that the DEA’s or Ohio BOP’s favorable conclusions about Giant Eagle’s compliance are unreliable or erroneous. Giant Eagle opened its books and facilities to the DEA and Ohio BOP for their 100-plus in-depth inspections, and there are no facts about Giant Eagle that were not known or available to these agencies *in real time* during their respective inspections. There is no evidence (or even allegation) that Giant Eagle did not utilize its controls against diversion exactly as they were described to the DEA and Ohio BOP, or that Giant Eagle ever withheld information from or misled these regulatory agencies in any way. *See* SJ-Exs. 4-5, 7 (2013, 2014, and 2017 DEA ROIs finding that Giant Eagle “provided all necessary records and information required to conduct this investigation.”).<sup>27</sup> To the contrary, the undisputed evidence shows that Giant Eagle cooperated extensively with the DEA, Ohio BOP, and law enforcement authorities in the fight against diversion. *See supra*, Section I.D.

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<sup>27</sup> *See also* SJ-Ex. 43 (DEA 30(b)(6) Tr. at 163:5-9) (“A diversion investigator would have the ability to review any documents that they’re – that they’re required to keep according to the regulations.”); *id.* at 249:19-23 (“Q. Is it a fair statement that the diversion investigators can request whatever documents they need to conduct their investigation? A. Yes.”).

While the Counties complain that Giant Eagle’s pre-October 2013 SOM system was a manual system, it is of no import to the DEA whether a SOM system is automated or manual. Nothing in the DEA’s security regulations requires (or has ever required) an automated SOM system, but rather, they permit and encourage registrants to design a SOM system that fits their business. SJ-Ex. 10 (Rafalski Tr. at 112:6-113:14, 327:15-16); SJ-Ex. 17 (DEA 30(b)(6) Tr. at 179:22-180:15, 446:18-447:14). To that end, the DEA grants each registrant broad discretion over (1) how, or whether, it documents its SOM procedures or due diligence, (2) how it conducts due diligence, and (3) how, or whether, it maintains SOM records. SJ-Ex. 29 (Ashley Tr. at 251:17–252:18, 253:6–254:5); *see also* SJ-Ex. 17 (DEA 30(b)(6) Tr. at 103:6-16, 108:23-109:4, 179:22–180:22. Even Mr. Rafalski himself previously found a manual SOM system compliant “based on [the] business activity and the abilities and knowledge of the employees.” SJ-Ex. 10 at 451:7-14.

It thus makes sense and is entirely appropriate that Giant Eagle’s system of anti-diversion controls is unique to its own business and did not implement the exact same flagging methodologies that the Counties created for this litigation, which even Mr. Rafalski admits he never used or recommended in practice. SJ-Ex. 10 at 84:18-85:3, 113:15-114:5. Of course, the DEA *knew* that Giant Eagle used a manual system, discussed it with Giant Eagle’s management, and nevertheless concluded Giant Eagle was in “full compliance” with all security regulations.

With respect to due diligence, and the alleged lack thereof, the Counties’ case is based almost entirely on the lack of a “paper record” existing *today* to show diligence conducted as far back as the mid-to-late 2000s. SJ-Ex. 10 (Rafalski Tr. at 344:21-345:16). But there is nothing in the CSA or its companion regulations that requires a registrant to document its due diligence actions, much less *retain* such documentation indefinitely to satiate the curiosity of opposing expert witnesses in potential future tort lawsuits. *See, e.g.*, SJ-Ex. 10 (Rafalski Tr. at 70:16-18,

280:4-7); SJ-Ex. 29 (Ashley Tr. at 252:5-254:5). The Counties’ reliance on the alleged lack of documented due diligence is particularly unsound where, as here, their own experts cannot even articulate the scope of any purported retention obligation. *See* SJ-Ex. 10 (Rafalski Tr. at 345:17-347:18) (unable to testify when records up to 30 years’ old can be destroyed and admitting that his views on document retention “also [are] not in the law.”).<sup>28</sup>

Given the lack of any requirement for Giant Eagle to maintain in perpetuity the records the Counties’ experts now demand to see, it is unsurprising that the DEA never informed Giant Eagle “that it was required to keep records of every call, every conversation that was made with respect to following up on orders of interest[.]” SJ-Ex. 19 (Giant Eagle 30(b)(6) Tr. at 295:14-20); SJ-Ex. 20 (Carlson Tr. at 200:2-24) (“There was nothing in the provision that said we had to keep documentation for any period of time on any investigation.”). Even more important, the DEA ROIs not only found Giant Eagle to be in “full compliance” with all security requirements, but also to be in “full compliance” with all DEA promulgated *recordkeeping* regulations. SJ-Ex. 4 (2013 ROI) (concluding that “both recordkeeping and security are in full compliance” and that Giant Eagle’s sales and distribution records “were maintained in accordance with the requirements set forth in Title 21 C.F.R. 1304.22(b).”); SJ-Ex. 5 (same); SJ-Ex. 7 (same).

Tellingly, despite his bald conclusion that Giant Eagle did not maintain effective controls against diversion, Mr. Rafalski did not consider any of the factors that he would have routinely considered when he was a DEA Diversion Investigator to determine whether any diversion was occurring at a Giant Eagle pharmacy. SJ-Ex. 10 at 122:20-124:16 (to determine whether a

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<sup>28</sup> The Counties’ experts’ reliance on a purported lack of documentation undermines Rule 702’s gatekeeping function and improperly imposes on Giant Eagle the burden of *disproving* the Counties’ case. *See Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 558 (W.D. Pa. 2003) (experts cannot draw conclusions simply because of an alleged lack of information, as doing so “would turn Rule 702 and *Daubert* on their heads by allowing the absence of reliable testing and data to support a causation opinion. Such an approach would also flip the relevant burdens - it is plaintiff who has the burden of proving causation and the reliability of her experts’ testimony.”).



pharmacy is a bad pharmacy, Rafalski would look at ordering patterns, prescribing patterns, types of drugs dispensed, controlled vs. non-controlled ratios, cash vs. non-cash payments, volume, geographic area, and other pharmacies nearby, but answering “I did not” when asked if he considered any of these factors in this case); *id.* at 351:17-352:9. Equally troubling, not one of the Counties’ experts considered the exculpatory testimony of Ohio BOP agents who actually inspected Giant Eagle’s pharmacies and found that they were operating lawfully at all times. *Id.* at 158:13-160:2; SJ-Ex. 12 (Catizone Tr. at 322:10-323:7). The record indicates that Giant Eagle did, in fact, undertake due diligence to address potential red flags. *See, e.g.*, SJ-Ex. 44 (Mooney Tr. at 103:7-108:3, 109:18-110:14, 322:1-327:9); *see also* SJ-Ex. 45 (Ashley Tr. at 64:15-65:3).

The Counties offer no evidence that even a single prescription filled by Giant Eagle was improperly dispensed or diverted in some other manner in the Counties. *See* SJ-Ex. 10 (Rafalski Tr. at 209:13-210:13). The Counties have no evidence that any of the thousands of orders identified in their flagging analysis were used to fill illegitimate prescriptions. *Id.* at 239:17-240:16, 431:14-21; *see also id.* at 43:24-44:4 (“Q. There is nothing at all in your report relating to the defendant pharmacies’ activities as pharmacies, i.e., filling prescriptions? A. That’s a correct statement, sir. There’s nothing in my report on that matter.”); SJ-Ex. 12 (Catizone Tr. at 167:12-168:5) (admitting same).

The failure to adduce any evidence of unlawful dispensing at the pharmacy level is not a minor proof problem. It is, rather, fatal to the Counties’ public nuisance claim even if they could prove that Giant Eagle lacked effective controls at the distribution level (which they cannot). As Mr. Rafalski necessarily concedes, in order to find that a self-distributor like Giant Eagle substantially contributed to an opioid epidemic, its pharmacies would have needed to *also* violate their obligations under state and federal law by improperly filling illegitimate prescriptions. SJ-

Ex. 10 at 108:22-109:3. Otherwise, there is no proof that *any* pills shipped from Giant Eagle’s warehouses were actually diverted and, in the absence such diversion, Giant Eagle could not have been a contributor (let alone a “substantial” contributor) to the alleged public nuisance.

**B. There is no evidence that Giant Eagle’s distribution or dispensing activities were a substantial cause of the alleged nuisance**

As explained above, the Counties cannot identify even a single pill distributed or dispensed by Giant Eagle that was diverted, much less offer proof that Giant Eagle’s conduct was a “substantial factor” in creating the alleged public nuisance. As such, *even if* the Counties could establish that Giant Eagle acted unlawfully (and they cannot), there is no proof that Giant Eagle’s conduct was a *proximate cause* of the alleged nuisance. The Counties, in fact, are explicitly *not* claiming that any specific pill distributed, or prescription filled, by Giant Eagle actually caused any harm to any individual or county. *See, e.g.*, Doc. # 3158 at 10. Mr. Rafalski disclaims even having an opinion about whether Giant Eagle’s pharmacies complied with their state and federal dispensing obligations (SJ-Ex. 10 at 403:20-22), and the Counties’ pharmacy expert, Catizone, has not made *any* effort to determine how many—if any—of the so-called “red flag” prescriptions were written for an illegitimate purpose and/or were actually diverted. SJ-Ex. 12 at 167:12-168:5, 417:4-420:25.

As if these gaping evidentiary holes were not enough to doom their causation theory, the Counties intentionally and entirely ignore the primary drivers of opioid diversion—namely, pill mill doctors and pharmacies, drug gangs, internet pharmacies, and medicine cabinet leakage. The Counties did not even consider the contribution of anyone or anything to the opioids epidemic in Lake and Trumbull Counties *other than* the five pharmacy defendants in this case, thereby creating a fictional world in which *only* these five pharmacy defendants dispensed or otherwise brought opioids into the Counties. SJ-Ex. 10 (Rafalski Tr. at 41:12-18); SJ-Ex. 12 (Catizone Tr. at 453:17-

454:1). In so arguing, the Counties ignore (if not flat-out contradict) their own complaints, which ascribe fault for the epidemic to drug manufacturers, the Big Three distributors, and other entities having nothing to do with Giant Eagle.

But the Counties cannot wish away or ignore the following undisputed (and indisputable) proof of the principal causes of the opioid epidemic in Lake and Trumbull Counties:

- The Counties ignore the effect of drug gangs from Detroit that brought huge quantities of opioids into the two counties, and which the Ohio State Highway Patrol found were the main source of illicit opioids in Northeast Ohio. SJ-Ex. 10 (Rafalski Tr. at 411:20-412:2).
- The Counties ignore the well documented role played by internet pharmacies in flooding the counties with illegitimate opioids. SJ-Ex. 10 (Rafalski Tr. at 408:4-8).
- The Counties ignore the role played by pill mill doctors within and affecting the counties. SJ-Ex. 10 (Rafalski Tr. at 399:1-7); Doc. # 3327 at ¶ 12 (alleging critical role played by “pill mills” and “rogue prescribers” in fostering actual diversion). Dr. Franklin alone, for example, wrote 15,000 illegitimate prescriptions in only two years. SJ-Ex. 10 (Rafalski Tr. at 407:8-408:3).
- The Counties ignore the role of direct prescriptions written and filled by doctors, which are not reported on OARRS. SJ-Ex. 10 (Rafalski Tr. at 194:5-13).
- The Counties ignore the contribution of out-of-state pain clinics, despite highlighting in their complaints the major role these clinics allegedly played in funneling opioids into Ohio. SJ-Ex. 10 (Rafalski Tr. at 207:18-208:25); Doc. # 3327 at ¶ 551.
- In concluding that the Pharmacy Defendants contributed to an alleged “oversupply” of opioids, the Counties ignore the fact that DEA quotas for opioids increased at near exponential rates during the relevant period. *See supra*.
- The Counties ignore the testimony of the Ohio BOP agents (1) that Giant Eagle was not a source of diversion, but rather, actively helped combat diversion and (2) describing the other actors that caused diversion in Lake and Trumbull Counties. SJ-Ex. 10 (Rafalski Tr. at 398:24-399:139).
- While the Counties allege that the existence of various drug task forces in Ohio illustrate the extent of the epidemic (*see* Doc. # 3327 at ¶ 580), the Counties ignore the undisputed fact that the drug task forces, which are formed with all types of experts specifically to combat opioid diversion/misuse, never mention Giant Eagle.

By purposefully ignoring other known major sources of diversion, the Counties cannot identify or quantify Giant Eagle's relative contribution (if any) to such diversion in a manner that would allow a jury to conclude that Giant Eagle was, in fact, a "substantial factor" in causing the public nuisance. SJ-Ex. 10 (Rafalski Tr. at 174:11-175:11); SJ-Ex. 12 (Catizone Tr. at 417:4-420:25). Thus, regardless of whether the Counties can establish that Giant Eagle violated the CSA (they cannot), they still cannot prove that any such violations were a substantial proximate cause of the alleged nuisance. This provides an additional basis for judgment in Giant Eagle's favor.

**C. At minimum, due to a complete failure of proof, Giant Eagle is entitled to partial summary judgment regarding its GERX distribution facility**

GERX only began distributing Schedule II controlled substances in 2016 after receiving a license from the DEA. SJ-Ex. 6. Despite reviewing extensive data, policies, and procedures, the Counties have nothing bad to say about GERX or its compliance with the DEA's security regulations. *See, e.g.*, SJ-Ex. 10 (Rafalski Tr. at 101:22-102:24) ("I have some information contained in my report, but I did not have enough information to make a definitive opinion on [Giant Eagle's] conduct post-2016. ... I do not have an opinion past 2014 on the SOMs issue.").

While the Counties have no evidence of non-compliance regarding GERX, there is ample evidence that GERX was a model distribution facility from a regulatory perspective. *See, e.g.*, SJ-Ex. 7 at US-DEA-00030417 ("full compliance"). Indeed, before transferring its distribution operations from HBC to GERX in early 2016, Giant Eagle electively sought and obtained approval from the National Association of Boards of Pharmacy (NABP) for Verified-Accredited Wholesale Distributors (VAWD) certification. SJ-Ex. 41 (Millward Tr. at 51:14-18; 70:16-71:12; 125:12-16; 212:6-18). As explained by the Counties' pharmacy expert, Mr. Catizone, VAWD accreditation means that the company's policies and procedures "are compliant with the CSA." SJ-Ex. 12 at 120:2-7 ("Q. And so at least from a policies and procedures standpoint, if the VAWD

is giving accreditation, it is concluding that their policies and procedures are compliant with the CSA, correct? [objection omitted] A. Along the distribution lines, yes.”). Indeed, as Mr. Catizone himself described it in his 2017 testimony to the Senate Committee on the Judiciary, the NABP can “confidently represent that those wholesale distributors who achieve accreditation”—like GERX—“have processes in place to comply with the Controlled Substances Act and Regulations *and are determined to be compliant with all federal and state laws.*” SJ-Ex. 42 (Catizone December 12, 2017 Testimony to U.S. Senate Committee on the Judiciary) (emphasis added).

### **CONCLUSION**

The Counties’ sue-first, ask-questions-later approach to this massive MDL has led them to sue the wrong pharmacy chain. Giant Eagle’s long record of “full compliance” with all applicable regulations leaves no doubt about this conclusion. The Court should enter summary judgment in Giant Eagle’s favor.

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Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on July 23, 2021, the foregoing was served via e-mail to the following:

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